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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/602,351 | 06/23/2000 | Barbara K. Finck | 2945-A | 1329 |

7590 04/22/2002

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| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | 13 |

DATE MAILED: 04/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/602,351 | FINCK ET AL. | |
| | Examiner | Art Unit | |
| | David S Romeo | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the c rresp ndence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6,8 and 11-18* is/are pending in the application.

4a) Of the above claim(s) *14-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,8 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-6,8 and 11-18* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4-6,8,10, 12*.
4) ☒ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

The preliminary amendment filed 12/21/2001 (Paper No. 9) has been entered. Claims 1-6, 8, 11-18 are pending.

Applicant's election without traverse of group II, claim(s) 1-13, to the extent that they are drawn to a method of treating ordinary psoriasis comprising administering TNFR:Fc, in Paper No. 11 is acknowledged.

Claims 14-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 12, 13 are indefinite over the recitation of "ordinary psoriasis". The term "ordinary" is a relative term which renders the claim indefinite. The term "ordinary" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Claim 3 is indefinite over the recitation of "baseline". The term "baseline" is a relative term which renders the claim indefinite. The term "baseline" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Claim 6 is indefinite over the recitation of "$mg/m^2$" because it is unclear what object possesses the property of "$m^2$". The metes and bounds are not clearly set forth. It is suggested that the claims recite "$mg/m^2$ of body surface area".

Claim 12 is indefinite over the recitation of "mg/kg" because it is unclear what object possess the property of "kg". The metes and bounds are not clearly set forth. It is suggested that the claim recite "mg/kg of patient body weight".

Claim 12 is indefinite over the recitation of "up to a maximum of 25 mg" because it is unclear if 25 mg is the maximum amount administered during the course of therapy or if 25 mg is the maximum amount administered per dose. The metes and bounds are not clearly set forth. It is suggested that the claims recite "25 mg/dose".

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 12, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by Applicants).

Barnes (u13) teaches that in chronic inflammatory diseases, such as asthma, rheumatoid arthritis, inflammatory bowel disease, and psoriasis, several cytokines recruit activated immune and inflammatory cells to the site of lesions, thereby amplifying and perpetuating the inflammatory state. These activated cells produce many other mediators of inflammation. See page 1066, left column, full paragraph 1. One ubiquitous transcription factor of particular importance in immune and inflammatory responses is nuclear factor-κB (NF-κB) (page 1066, paragraph bridging left and right columns, last sentence). NF-κB regulates the expression of many genes involved in immune and inflammatory responses (page 1067, left column, full paragraph 1). NF-κB acts on genes for proinflammatory cytokines (including TNF-α), chemokines (chemotactic cytokines that attract inflammatory cells to sites of inflammation), enzymes that generate mediators of inflammation, immune receptors, and adhesion molecules that play a key part in the initial recruitment of leukocytes to sites of inflammation. The activation of NF-κB therefore leads to a coordinated increase in the expression of many genes whose products mediate inflammatory and immune responses. For example, the coordinated

stimulation of the expression of the genes for E-selectin, interleukin-8, and tumor necrosis factor (TNF-α) results in the recruitment and activation of neutrophils. See page 1067, left column, full paragraphs 1-2, Table 2, and Figure 2. The production of interleukin-1, TNF-α, interleukin-6, granulocyte–macrophage colony-stimulating factor, and many chemotactic cytokines (chemokines) is increased in patients with asthma, rheumatoid arthritis, psoriasis, and inflammatory bowel disease. All these cytokines have important roles in the inflammatory process. Interleukin-1 and TNF-α may influence the severity of disease, possibly by the persistent activation of NF-B. The treatment of patients with rheumatoid arthritis with antibodies to TNF-α can control refractory disease. See page 1067, paragraph bridging left and right columns. Barnes does not teach the treatment of psoriasis with TNFR:Fc.

Moreland (u13) teaches that tumor necrosis factor (TNF) is a proinflammatory cytokine involved in the pathogenesis of rheumatoid arthritis, and antagonism of TNF may reduce the activity of the disease. Moreland evaluated the safety and efficacy of a novel TNF antagonist -- a recombinant fusion protein that consists of the soluble TNF receptor (p75) linked to the Fc portion of human IgG1 (TNFR:Fc). Treatment with TNFR:Fc led to significant reductions in disease activity, and the therapeutic effects of TNFR:Fc were dose-related. See page 141, column 1, Background and Results. Moreland teaches the administration by subcutaneous injection twice weekly for a period of three months of 0.25, 2, and 16 mg TNFR:Fc per square meter of body surface area (page 142, right column, "Treatment"). TNFR:Fc produced significant improvement in all measures of disease activity, and a clear dose–response relation was observed (page 143, right column, full paragraph 1, and Figures 1 and 2). Moreland does not teach the treatment of psoriasis with TNFR:Fc.

Mandell teaches that psoriasis is among the conditions that can be treated or alleviated by the inhibition of IL-1, TNF, and other leukocyte derived cytokines. See paragraph bridging columns 7-8. Mandell does not teach the treatment of psoriasis with TNFR:Fc.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to treat or alleviate psoriasis by administering TNFR:Fc, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to combine these teachings because psoriasis is among the conditions that can be treated or alleviated by the inhibition of TNF, in chronic inflammatory diseases, such as asthma, rheumatoid arthritis, inflammatory bowel disease, and psoriasis, several cytokines recruit activated immune and inflammatory cells to the site of lesions, thereby amplifying and perpetuating the inflammatory state, the production of TNF-α is increased in patients with psoriasis, TNF-α has an important role in the inflammatory process, the treatment of patients with rheumatoid arthritis with antibodies to TNF-α can control refractory disease, and TNFR:Fc is safe and efficacious for the neutralization of TNF-α and the treatment of disease. With respect to the amounts administered in claims 6, 12, 13, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to administer such doses with a reasonable expectation of success. Generally, differences in dosages will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such dosages are critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable dosages by routine experimentation. In the present case there is no evidence of the criticality of the claimed dosages. Furthermore, Moreland, in teaching that a clear dose–response relation was observed, recognizes that response is a function of dose and,

thus, recognizes that dose is a result-effective variable, i.e., a variable which achieves a recognized result, and thus suggests proportional dosing of a patient, or of an adult or pediatric patient, to achieve the desired results in the neutralization of TNF-α.

It would have been further obvious to one of ordinary skill in the art at the time of Applicants' invention to vary the amount and frequency of administration depending, of course, on such factors as the nature and severity of the indication being treated, the desired response, the condition of the patient, and so forth. For example, Jacobs (U.S. Patent No. 5605690) teaches that for therapeutic use, purified soluble TNFR protein is administered to a patient, preferably a human, for treatment of arthritis. Thus, for example, soluble TNFR protein compositions can be administered, for example, via intra-articular, intraperitoneal or subcutaneous routes by bolus injection, continuous infusion, sustained release from implants, or other suitable techniques (column 13, lines 28-35). For treatment of arthritis, TNFR is administered in systemic amounts ranging from about 0.1 mg/kg/week to about 100 mg/kg/week. In preferred embodiments of the present invention, TNFR is administered in amounts ranging from about 0.5 mg/kg/week to about 50 mg/kg/week. For local intra-articular administration, dosages preferably range from about 0.01 mg/kg to about 1.0 mg/kg per injection. See column 14, lines 3-9. The amount and frequency of administration will depend, of course, on such factors as the nature and severity of the indication being treated, the desired response, the condition of the patient, and so forth (column 13, lines 52-55).

An improvement over baseline in an indicator selected from the group consisting of psoriasis area and severity index (PASI) and Target Lesion Assessment Score would naturally follow from following the teachings of the prior art.

The invention is prima facie obvious over the prior art.

Claims 1, 2, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by Applicants) as applied to claims 1, 2 above, and further in view of Wallach (a13, U.S. Patent No. 6083534).

Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by Applicants) teach the administration of TNFR:Fc for the treatment of psoriasis, as discussed above. Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by Applicants) do not teach administration of TNFR:Fc in a sustained release form.

Jacobs (U.S. Patent No. 5605690) teaches that for therapeutic use, purified soluble TNFR protein is administered to a patient, preferably a human, for treatment of arthritis. Thus, for example, soluble TNFR protein compositions can be administered, for example, via intra-articular, intraperitoneal or subcutaneous routes by bolus injection, continuous infusion, sustained release from implants, or other suitable techniques (column 13, lines 28-35).

Wallach (U.S. Patent No. 6083534) teaches that a controlled release pharmaceutical composition that includes a biocompatible polymeric material, preferably polyethylene-vinyl acetate or poly(lactic-glucolic acid), having incorporated therein a soluble receptor capable of binding to its ligand and thus affecting the ligand's function. The soluble receptor is preferably the soluble form of TNF-α receptor. Such compositions are for use in the treatment of disorders in which neutralization of the deleterious effects of TNF-α is required. See the Abstract.

Controlled release systems deliver a drug at a predetermined rate for a definite time period, that may range from days to years. These systems provide advantages over conventional drug therapies. See column 1, lines 19-36. Wallach teaches approaches for therapeutic applications of soluble forms of receptors for affecting the functions of their ligands, e.g., for protection against deleterious effects of their ligands, particularly systems which allow local release of the soluble receptor in the body, at a constant rate and for long duration. These approaches are based on incorporation of the soluble receptor into biocompatible polymeric materials, which are implanted or injected in desired bodily compartments. Matrices of polymers containing the soluble receptor enable local and controlled release of the soluble receptor, in its natural form. Any soluble receptor that is capable of binding to and affecting the functions of its ligand, either neutralizing the deleterious effects of its ligand and/or stabilizing or augmenting its activity, is encompassed by the invention. Examples of such soluble receptors are the soluble receptors of hormones and of cytokines, and in a preferred embodiment, the soluble receptor is a soluble TNF receptor. See column 3, line 55, through column 4, line 8, and column 4, lines 38-45. Wallach teaches that the pharmaceutical composition of the invention comprising a sTNF-R may be used to neutralize the deleterious effects of TNF in autoimmune diseases such as rheumatoid arthritis (column 7, lines 38-47). Wallach teaches that the compositions for treatment of rheumatoid arthritis may comprise other anti-inflammatory agents (column 7, lines 56-57).

There are no limiting definitions of "a semi-permeable implant". Either the sustained release from implants, as taught by Jacobs, or the controlled release pharmaceutical composition, as taught by Wallach, is a semi-permeable implant in the absence of a limiting definition of a semi-permeable implant.

Jacobs and Wallach do not teach administration of TNFR:Fc in a sustained release form that is encapsulated or admixed with a biocompatible polymer or that is encased in a semi-permeable implant.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to treat psoriasis with TNFR:Fc, as taught by Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by Applicants), and to modify that teaching by administering the TNFR:Fc in a sustained release form that is encapsulated or admixed with a biocompatible polymer or that is encased in a semi-permeable implant, as taught by Jacobs and Wallach, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to combine these teachings because controlled release systems provide advantages over conventional drug therapies. The invention is prima facie obvious over the prior art.

Claims 1, 2, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by Applicants) as applied to claims 1, 2 above, and further in view of Pamukcu (b13) and Feldman (w13).

Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by Applicants) teach the administration of TNFR:Fc for the treatment of psoriasis, as discussed above. Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by

Applicants) do not teach administration of TNFR:Fc concurrently with psoralen combined with ultraviolet light A.

Pamukcu teaches that photochemotherapy (PUVA) (an acronym for the combination of the drug Psoralen with Ultraviolet A Light) is used to treat moderate to severe psoriasis, as well as disabling psoriasis that cannot be controlled by other means. The drug psoralen is activated by the skin's exposure to ultraviolet light (UVA). PUVA can be used to treat the whole body or specific skin sites such as the hands and feet. It can also be combined with other psoriasis therapies. See column 2, full paragraph 5.

Feldman teaches that the most effective therapy in immune inflammatory diseases will come from therapy aimed at several points in the disease pathway. Such combination therapies, if given early in the course of the disease process, may be able to control the disease. See page 4127, left column, full paragraph 1.

Pamukcu and Feldman do not teach the administration of TNFR:Fc for the treatment of psoriasis.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to administer TNFR:Fc for the treatment of psoriasis, as taught by Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by Applicants), and to modify that teaching by administering TNFR:Fc concurrently with PUVA, as taught by Pamukcu, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to combine these teachings because PUVA can also be combined with other psoriasis therapies and the most effective therapy in

immune inflammatory diseases will come from therapy aimed at several points in the disease pathway.

The invention is prima facie obvious over the prior art.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 8, 11-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,605,690. Although the conflicting claims are not identical, they are not patentably distinct from each other because a chimeric antibody comprising a TNF receptor fused to the constant region of an immunoglobulin molecule of the patent is a TNFR:Fc of the present application. It necessarily follows that lowering the levels of TNF-α in a mammal covers the administration of TNFR:Fc to treat psoriasis. The only discernible difference between the claims of the patent and the claims of the present application is that the former addresses the treatment of TNF-α levels in mammals while the latter addresses the treatment of psoriasis in humans. Humans are a species of the animal genus, and psoriasis is a species of ailment of the genus of ailments caused by elevated

TNF-α levels. Psoriasis occurs in humans and it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to lower the TNF-α levels in mammal wherein the mammal is a human and the human has psoriasis, as evidenced by the prior art rejections of record.

Alternatively, Claims 1-6, 12, 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,605,690 in view of Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by Applicants). A chimeric antibody comprising a TNF receptor fused to the constant region of an immunoglobulin molecule of the patent is a TNFR:Fc of the present application. It necessarily follows that lowering the levels of TNF-α in a mammal covers the administration of TNFR:Fc to treat psoriasis. The only discernible difference between the claims of the patent and the claims of the present application is that the former addresses the treatment of TNF-α levels in mammals while the latter addresses the treatment of psoriasis in humans. The teachings of Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by Applicants) are discussed above and incorporated herein by reference. It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to treat or alleviate psoriasis by administering TNFR:Fc, with a reasonable expectation of success.

Alternatively, Claims 1, 2, 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No.

5,605,690 in view of Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by Applicants) as applied to claims 1, 2 above, and further in view of Wallach (a13, U.S. Patent No. 6083534). A chimeric antibody comprising a TNF receptor fused to the constant region of an immunoglobulin molecule of the patent is a TNFR:Fc of the present application. It necessarily follows that lowering the levels of TNF-α in a mammal covers the administration of TNFR:Fc to treat psoriasis. The only discernible difference between the claims of the patent and the claims of the present application is that the former addresses the treatment of TNF-α levels in mammals while the latter addresses the treatment of psoriasis in humans. The teachings of Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by Applicants) as applied to claims 1, 2 above, and further in view of Wallach (a13, U.S. Patent No. 6083534) are discussed above and incorporated herein by reference. Administering the TNFR:Fc in a sustained release form that is encapsulated or admixed with a biocompatible polymer or that is encased in a semi-permeable implant would have been obvious to one of ordinary skill in the art at the time of Applicants' invention with a reasonable expectation of success.

Alternatively, Claims 1, 2, 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,605,690 in view of Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by Applicants) as applied to claims 1, 2 above, and further in view of Pamukcu (b13) and Feldman (w13). A chimeric antibody

comprising a TNF receptor fused to the constant region of an immunoglobulin molecule of the patent is a TNFR:Fc of the present application. It necessarily follows that lowering the levels of TNF-α in a mammal covers the administration of TNFR:Fc to treat psoriasis. The only discernible difference between the claims of the patent and the claims of the present application is that the former addresses the treatment of TNF-α levels in mammals while the latter addresses the treatment of psoriasis in humans. The teachings of Barnes (u13), Moreland (v13), Mandell (U.S. Patent No. 4965271, cited by Applicants), and Jacobs (U.S. Patent No. 5605690, cited by Applicants) as applied to claims 1, 2 above, and further in view of Pamukcu (b13) and Feldman (w13) are discussed above and incorporated herein by reference. It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to administer TNFR:Fc for the treatment of psoriasis and to modify that teaching by administering TNFR:Fc concurrently with PUVA with a reasonable expectation of success.

***Conclusion***

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
APRIL 20, 2002